

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

WARNER CHILCOTT COMPANY, LLC, and
HOFFMANN-LA ROCHE INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.

Defendant.

C.A. No. 08-627-LPS

C.A. No. 11-81-LPS

WARNER CHILCOTT COMPANY, LLC, and
HOFFMANN-LA ROCHE INC.,

Plaintiffs,

v.

APOTEX, INC. and APOTEX CORP.

Defendant.

REDACTED
PUBLIC VERSION

C.A. No. 09-143-LPS

C.A. No. 10-1111-LPS

WARNER CHILCOTT COMPANY, LLC, and
HOFFMANN-LA ROCHE INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC.

Defendant.

C.A. No. 10-285-LPS

C.A. No. 11-286-LPS

WARNER CHILCOTT COMPANY, LLC, and
HOFFMANN-LA ROCHE INC.,

Plaintiffs,

v.

SUN PHARMA GLOBAL FZE,

Defendant.

C.A. No. 09-61-LPS
C.A. No. 10-1085-LPS

**DECLARATION OF JACLYN C. LEVY, ESQ. IN SUPPORT OF
PLAINTIFFS WARNER CHILCOTT COMPANY, LLC AND
HOFFMANN-LA ROCHE INC.'S BRIEF IN SUPPORT OF OPPOSITION TO
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF INVALIDITY FOR
OBVIOUSNESS UNDER 35 U.S.C. § 103**

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Attorneys for Plaintiff Warner Chilcott LLC

Dated: July 20, 2012

I, Jaclyn C. Levy, declare as follows:

1. I am an attorney at the law firm of Richards, Layton & Finger, P.A., counsel representing Plaintiffs Warner Chilcott Company, LLC, and Hoffmann-La Roche, Inc. (“Plaintiffs”) in the above-captioned action.

2. I am admitted to practice before this Court.

3. I submit this declaration in support of Plaintiffs’ Brief In Opposition to Defendant’s Motion For Summary Judgment of Invalidity for Obviousness Under 35 U.S.C. § 103.

4. Attached hereto as Exhibit 1 is a true and correct copy of the August 5, 2011 deposition transcript of Frieder Bauss in Hoffman-La Roche Inc. v. Apotex Inc. and Apotex Corp., Civil Action No. 07-4417-SRC (D. N.J.) (consolidated).

5. Attached hereto as Exhibit 2 is a true and correct copy of the October 5, 2011 deposition transcript of Maurice Gately in this matter.

6. Attached hereto as Exhibit 3 is a true and correct copy of the June 30, 2011 deposition transcript of Pamela Schofield in this matter.

7. Attached hereto as Exhibit 4 is a true and correct copy of an excerpt of document produced by Plaintiff Warner Chilcott Co. LLC as PGOAM 0381085.

8. Attached hereto as Exhibit 5 is a true and correct copy of U.S. Patent No. 7,192,938 (“the ‘938 patent”).

9. Attached hereto as Exhibit 6 is a true and correct copy of U.S. Patent No. 7,718,634 (“the ‘634 patent”).

10. Attached hereto as Exhibit 7 is a true and correct copy of Lufkin *et al.*, *Pamidronate: An Unrecognized Problem in Gastrointestinal Tolerability*, Osteoporosis Int'l 4:320-22 (1994).

11. Attached hereto as Exhibit 8 is a true and correct copy of DeGroen *et al.*, *Esophagitis Associated with the Use of Alendronate*, New Eng. J. Med. 335:1016-21 (1996).

12. Attached hereto as Exhibit 9 is a true and correct copy of Schnitzer, *Update on Alendronate for Osteoporosis: Once-Weekly Dosing*, Expert Opin. Pharmacother. 2:1461-72, 1467 (2001).

13. Attached hereto as Exhibit 10 is a true and correct copy of Lanza *et al.*, *The Upper GI Safety and Tolerability of Oral Alendronate at a Dose of 70 Milligrams Once Weekly: A Placebo-Controlled Endoscopy Study*, Am. J. Gastroenter. 97:58-64 (2002).

14. Attached hereto as Exhibit 11 is a true and correct copy of Intl. Pub. No. WO 01/15703.

15. Attached hereto as Exhibit 12 is a true and correct copy of Suri *et al.*, *Nitrogen-Containing Bisphosphonates Induce Apoptosis of Caco-2 Cells In Vitro by Inhibiting the Mevalonate Pathway: A Model of Bisphosphonate-Induced Gastrointestinal Toxicity*, Bone 29:336-43 at 338 (2001).

16. Attached hereto as Exhibit 13 is a true and correct copy of Lanza *et al.*, *Endoscopic Comparison of Esophageal and Gastroduodenal Effects of Risedronate and Alendronate in Postmenopausal Women*, Gastroenterol. 119:631-38 (2000).

17. Attached hereto as Exhibit 14 is a true and correct copy of the Fosamax® Label (Jan. 31, 2001).

18. Attached hereto as Exhibit 15 is a true and correct copy of the Actonel® Label (Apr. 14, 2000).

19. Attached hereto as Exhibit 16 is a true and correct copy of U.S. Patent No. 5,994,329.

20. Attached hereto as Exhibit 17 is a true and correct copy of U.S. Patent Publ'n. No. 2003/0118634.

21. Attached hereto as Exhibit 18 is a true and correct copy of Lindsay et al., *Risedronate 35 mg Once A Week Is As Effective As 5 mg Daily in Postmenopausal Women*, *Arthr. & Rheum.* 9(suppl.):S153, 604 (2001).

22. Attached hereto as Exhibit 19 is a true and correct copy of a document produced by Plaintiff Warner Chilcott Co. LLC as PGOAM_E1012284-86.

23. Attached hereto as Exhibit 20 is a true and correct copy of U.S. Patent Publ'n. No. 2002/0002282.

24. Attached hereto as Exhibit 21 is a true and correct copy of Intl. Pub. No. WO 01/82903.

25. Attached hereto as Exhibit 22 is a true and correct copy of U.S. Patent No. 6,468,559.

26. Attached hereto as Exhibit 23 is a true and correct copy of a document produced by Defendants Apotex Corp. and Apotex Inc. (collectively, "Apotex") as AP-RISE0007768-76.

27. Attached hereto as Exhibit 24 is a true and correct copy of a document produced by Defendant Apotex as AP-RISE0007877-83.

28. Attached hereto as Exhibit 25 is a true and correct copy of a document produced by Defendant Apotex as AP-RISE0007782-98.

29. Attached hereto as Exhibit 26 is a true and correct copy of a document produced by Defendant Apotex as AP-RISE0007888-7901.

30. Attached hereto as Exhibit 27 is a true and correct copy of a document produced by Defendant Apotex as AP-RISE0008331-33.

31. Attached hereto as Exhibit 28 is a true and correct copy of Rosen, *Treatment of Postmenopausal Osteoporosis: An Evidence-Based Approach*, Rev. Endocr. & Metab. Disord. 2:35-43 (2001).

32. Attached hereto as Exhibit 29 is a true and correct copy of a document produced by Plaintiff Roche as R2012805-21.

33. Attached hereto as Exhibit 30 is a true and correct copy of a document produced by Defendant Apotex as AP-RISE0007712-18.

34. Attached hereto as Exhibit 31 is a true and correct copy of a document produced by Defendants as AP-RISE0004548-54.

35. Attached hereto as Exhibit 32 is a true and correct copy of a document produced by Defendant Apotex as AP-RISE0007724-32.

36. Attached hereto as Exhibit 33 is a true and correct copy of a document produced by Defendant Apotex as AP-RISE0004681, 0004674-77, 0004656-58.

37. Attached hereto as Exhibit 34 is a true and correct copy of a document produced by Defendant Apotex as AP-RISE0004693

38. Attached hereto as Exhibit 35 is a true and correct copy of Riis et al., *Ibandronate: A Comparison of Oral Daily Dosing Versus Intermittent Dosing in Postmenopausal Osteoporosis*, J. Bone & Min. Res. 16:1871-78 (2001).

39. Attached hereto as Exhibit 36 is a true and correct copy of Zegels et al., *Effect of High Doses of Oral Risedronate (20 mg/day) on Serum Parathyroid Hormone Levels and Urinary Collagen Cross-link Excretion in Postmenopausal Women with Spinal Osteoporosis*, Bone 28:108-12 (2001).

40. Attached hereto as Exhibit 37 is a true and correct copy of Delmas et al., *Bisphosphonate Risedronate Prevents Bone Loss in Women with Artificial Menopause Due to Chemotherapy of Breast Cancer: A Double-Blind, Placebo-Controlled Study*, J. Clin. Oncol. 15:955-62 (1997).

41. Attached hereto as Exhibit 38 is a true and correct copy of Harris et al., *Effects of Risedronate Treatment on Vertebral and Nonvertebral Fractures in Women with Postmenopausal Osteoporosis: A Randomized Controlled Trial*, JAMA 282:1344-52, 1348 (1999).

42. Attached hereto as Exhibit 39 is a true and correct copy of Bone et al., *Weekly Administration of Alendronate: Rationale and Plan for Clinical Assessment*, Clin. Ther. 22:15-28, 17 (2000).

43. Attached hereto as Exhibit 40 is a true and correct copy of U.S. Patent No. 6,432,932.

44. Attached hereto as Exhibit 41 is a true and correct copy of Schnitzer et al., *Therapeutic Equivalence of Alendronate 70 mg Once-Weekly and Alendronate 10 mg Daily in the Treatment of Osteoporosis*, Aging Clin. Exp. Res. 12:1-12 (2000).

45. Attached hereto as Exhibit 42 is a true and correct copy of Yates et al., *Alendronate and Osteoporosis*, Drug Discovery Today, Vol. 3, No. 2, pp. 69-78, at 70 (Feb. 1998).

46. Attached hereto as Exhibit 43 is a true and correct copy of U.S. Patent App'n Publ'n 2003/0195171.

47. Attached hereto as Exhibit 44 is a true and correct copy of a document produced by Plaintiff Warner Chilcott Co. LLC as PGOAM 0381086-0381098.

48. Attached hereto as Exhibit 45 is a true and correct copy of an excerpt from a document produced by Plaintiff Warner Chilcott Co. LLC as PGOAM 0377918.

49. Attached hereto as Exhibit 46 is a true and correct copy of an excerpt from the August 30, 2011 Deposition Transcript of April Mitchell.

50. Attached hereto as Exhibit 47 is a true and correct copy of an excerpt of a document produced by Plaintiff Warner Chilcott Co. LLC as PGOAM_E1294894-991.

51. Attached hereto as Exhibit 48 is a true and correct copy of *Bisphosphonates in Bone Disease, From the Laboratory to the Patient*, Fleisch (2000).

52. Attached hereto as Exhibit 49 is a true and correct copy of Lin, J.H., *Bisphosphonates: A Review of Their Pharmacokinetic Properties*, BONE, Vol. 18, No. 2 (Feb. 1996).

53. Attached hereto as Exhibit 50 is a true and correct copy of Janner et al., *Sodium EDTA Enhances Intestinal Absorption of Two Bisphosphonates*, Calcif. Tissue Int., Vol. 49, pp. 280-83 (1991).

54. Attached hereto as Exhibit 51 is a true and correct copy of Boulenc et al., *Bisphosphonates Increase Tight Junction Permeability in the Human Intestinal Epithelial (Caco-2) model*, Int. J. of Pharmaceutics 123, Vol. 13, No. 24 (1995).

55. Attached hereto as Exhibit 52 is a true and correct copy of Boulenc et al., *Importance of the Paracellular Pathway for the Transport of a New Bisphosphonate Using the Human Caco-2 Monolayers Model*, Biochemical Pharmacol., Vol. 46, No. 9 (1993).

56. Attached hereto as Exhibit 53 is a true and correct copy of Recker & Saville, *Intestinal Absorption of Disodium Ethane-1-hydroxy-1, 1-diphosphonate (Disodium Etidronate) Using a Deconvolution Technique*, Tox. and Applied Pharm., Vol. 24 (1973).

57. Attached hereto as Exhibit 54 is a true and correct copy of Lin et al., *On the Absorption of Alendronate in Rats*, J. of Pharm. Sciences, Vol. 83, No. 12 (1994).

58. Attached hereto as Exhibit 55 is a true and correct copy of Gertz et al., *Studies of the Oral Bioavailability of Alendronate*, Clin. Pharm. & Ther., Vol. 58, No. 3 (Sept. 1995).

59. Attached hereto as Exhibit 56 is a true and correct copy of Mitchell et al., *The Effect of Dosing Regimen on the Pharmacokinetics of Risedronate*, J. Clin. Pharmacol., Vol. 48, pp. 536-42 (1999).

60. Attached hereto as Exhibit 57 is a true and correct copy of Burgio et al., *Risedronate Pharmacokinetics Following Daily (5MG/Day) and Weekly (35 and 50 MG/Week) Oral Dosing Regimens to Postmenopausal Women*, Clin. Pharmacol. & Ther., Vol. 71, No. 2 (Feb. 2002).

61. Attached hereto as Exhibit 58 is a true and correct copy of Ravn et al., *The Effect on Bone Mass and Bone Markers of Different Doses of Ibandronate: A New Bisphosphonate for Prevention and Treatment of Postmenopausal Osteoporosis: A 1-Year, Randomized, Double-Blind, Placebo-Controlled Dose-Finding Study*, Bone, Vol. 19, No. 5 (Nov. 1996).

62. Attached hereto as Exhibit 59 is a true and correct copy of Sansom et al., *Human Pharmacokinetics of Tiludronate*, Bone, Vol. 17, No. 5 (Supplement) (Nov. 1995).

63. Attached hereto as Exhibit 60 is a true and correct copy of Usui et al., *Pharmacokinetics of YM175, A New Bisphosphonate, in Rats and Dogs, Drug Metabolism and Disposition*, Vol. 23, No. 11 (1995).

64. Attached hereto as Exhibit 61 is a true and correct copy of Gural et al., *Dose-dependent Absorption of Disodium Etidronate*, J. Pharm. Pharmacol., Vol. 37, pp. 443-45 (1985).

65. Attached hereto as Exhibit 62 is a true and correct copy of Mitchell et al., *Dose-Proportional Pharmacokinetics of Risedronate on Single-Dose Oral Administration to Healthy Volunteers*, J. Clin. Pharmacol., Vol. 40, No. 3 (March 2000).

66. Attached hereto as Exhibit 63 is a true and correct copy of Cheung et al., *A Single-Dose Bioavailability Study of Pamidronate Disodium After Oral Administration as Encapsulated Enteric-Coated Pellets, Enteric-Coated Tablets, and a Solution to Patients With Postmenopausal Osteoporosis*, Am. J. of Therapeutics, Vol. 1, pp. 221-27 (1994).

67. Attached hereto as Exhibit 64 is a true and correct copy of Reid et al., *Intravenous Zoledronic Acid in Postmenopausal Women With Low Bone Mineral Density*, N. Engl. J. Med., Vol. 346, No. 9 (Feb. 2002).

68. Attached hereto as Exhibit 65 is a true and correct copy of Intl. Pub. No. WO 01/97788.

69. Attached hereto as Exhibit 66 is a true and correct copy of Mitchell et al., *Risedronate Pharmacokinetics and Intra- and Inter-Subject Variability Upon Single-Dose Intravenous and Oral Administration*, Pharm. Res., Vol. 18, No. 2 (2001).

70. Attached hereto as Exhibit 67 is a true and correct copy of Chen et al., *Pharmacokinetics and Pharmacodynamics of Zoledronic Acid in Cancer Patients With Bone Metastases*, J. Clin. Pharmacol., Vol. 42 (2002).

71. Attached hereto as Exhibit 68 is a true and correct copy of Hyldstrup et al., *Pharmacokinetic Evaluation of Pamidronate After Oral Administration: A Study on Dose Proportionality, Absolute Bioavailability, and Effect of Repeated Administration*, Calcif. Tissue Int., Vol. 53, pp. 297-300 (1993).

72. Attached hereto as Exhibit 69 is a true and correct copy of Reginster, *Oral Tiludronate: Pharmacological Properties and Potential Usefulness in Paget's Disease of Bone and Osteoporosis*, Bone, Vol. 13, pp. 351-54 (1992).

73. Attached hereto as Exhibit 70 is a true and correct copy of Yakatan et al., *Clodronate Kinetics and Bioavailability*. Clin. Pharmacol. & Ther., Vol. 31, No. 3 (Mar. 1982).

74. Attached hereto as Exhibit 71 is a true and correct copy of Conrad et al., *Clodronate Kinetics and Dynamics*. Clin. Pharmacol. & Ther., Vol. 30, No. 1 (Jul. 1981).

75. Attached hereto as Exhibit 72 is a true and correct copy of Powell and DeMark, *Clinical Pharmacokinetics of Diphosphonates, Bone Resorption, Metastasis, and Diphosphonates* (1985).

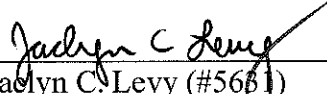
76. Attached hereto as Exhibit 73 is a true and correct copy of Bone et al., *Weekly Administration of Alendronate: Rationale and Plan for Clinical Assessment*. Clin. Ther., Vol. 22, No. 1 (2000).

77. Attached hereto as Exhibit 74 is a true and correct copy of Mitchell et al., *Effect of Renal Function on Risedronate Pharmacokinetics After a Single Oral Dose*. Br. J. Clin. Pharmacol., Vol. 49 (2000).

78. Attached hereto as Exhibit 75 is a true and correct copy of Mitchell et al., *Bioavailability of Immediate-Release And Delayed-Release Risedronate Formulations Upon Oral Administration to Healthy Male Subjects in Fasted and Fed State*, Pharm. Res., 13:S458 (1996).

79. Attached hereto as Exhibit 76 is a true and correct copy of Mitchell et al., *Risedronate Gastrointestinal Absorption is Independent of Site and Rate of Administration*, Pharm. Res., Vol. 15, No. 2 (1998).

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge, information, and belief. Executed on July 20, 2012 in Wilmington, Delaware.


Jaelyn C. Levy (#5661)

CERTIFICATE OF SERVICE

I hereby certify that, on July 20, 2012, I electronically filed the foregoing document with the Clerk of Court using CM/ECF, which will send notification of such filing(s), and have sent a true and correct copy by electronic mail to the following:

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CERTIFICATE OF SERVICE

I hereby certify that, on July 27, 2012, a true and correct copy of the foregoing document was caused to be served on counsel of record at the following address as indicated:

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